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K003965

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

MRI SAFE INSTRUMENTS

December 8, 2000

COMPANY: Aesculap®, Inc.
944 Marcon Blvd.
Allentown, PA 18109

CONTACT: Lisa M. Millington, Regulatory Associate
800-258-1946 (phone)
610-231-3713 (fax)
lisa.millington@aesculap.com (email)

TRADE NAME: MRI Safe Instruments

COMMON NAME: MRI Safe Instruments

DEVICE CLASS: CLASS 1 – EXEMPT: CLASS II - PRE-EXEMPT 1976

PRODUCT CODE: Various (see table on next page)

CLASSIFICATION: Various (see table on next page)

REVIEW PANEL: Radiology

INTENDED USE

The MRI Safe Instruments are intended to be used with 1.5 Tesla equipment in (or lower field strength) magnetic resonance imaging procedures.

DEVICE DESCRIPTION

Aesculap's MRI Safe Instruments are comprised of a variety of non-sterile, reusable scissors, scalpels, retractors, needle holders, curettes, spatulas and forceps. These instruments are used to cut, manipulate, and grasp tissue while exposed to MRI Procedures.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for MRI Safe devices. The new MRI Safe Instruments conforms with applicable ASTM and ISO standards.

(Reference: A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems)

SUBSTANTIAL EQUIVALENCE

The MRI Safe Instruments are substantially equivalent in their intended use, labeling, and basic operating principles to the following predicate devices:

- Aesculap Yasargil Titanium Anerusym Clip (K970050)
- Daum MRI/Conventional Biopsy Kit (991366)
- Cook MRI Needles (K963565)

Table 1: MRI Instruments Listing:

Catalog #	Instrument Name	Device Class	Product Code	Classification
BA221K	Scalpel	I-Exempt	GDX	878.4800 – Scalpel, one piece
BC273K FD037K FD043K	Scissors Micro Scissors	I-Exempt	LRW	878.4800 Scissors, Surgical, General Use
BD047K BD547K FD214K FD216K BD880K	Dissecting Forceps Tissue Forceps Forceps	I-Exempt	GEN	878.4800 Forceps, General & Plastic
BH111K	Haemostatic Forceps	I-Exempt	HRQ	878.4800—Hemostat
GF783K GF784F GF792K	Suction Instruments	I-Exempt	GEA	878.4800 Cannula, Surgical, General & Plastics
FG735K FG733K	Bone Punch	I-Exempt	GXJ	882.4750 – Punch, Skull
BV067K BV250K BT363K	Retractor	I-Exempt	GAD	878.4800 Retractor, Surgical, General & Plastics
BB075K	Scalpel Handle	I-Exempt	GDZ	878.4750 – Handle, Scapel
BB515K	Scalpel Blade	I-Exempt	GES	878.4800 – Blade, Scalpel
BM033K BM066K	Needle Holder	I-Exempt	HXK	888.4540 Holder, Needle Orthopedic
FF292K FF293K	Dissector	I-Exempt	GDI	878.4800 Dissector, Surg, General & Plastics
FK360K	Raspatory	I-Exempt	HTR	878.4800 – Rasp
OL165K	Raspatory	I-Exempt	GAC	878.4800 – Rasp
OL623K	Retractor	I-Exempt	GDG	878.4800 Hook, Surg. General & Plastic
FF480K FF482K FF484K FF486K FF488K	Brain Spatula	I-Exempt	GAF	878.4800 Spatula, Surgical, General & Plastics
FL070K	Hammer	I-Exempt	HXL	878.4800 – Mallet
OL302K	Chisel	I-Exempt	HWM	878.4800 – Osteotome
FF591K OK038K OK088K OK0113K	Specula	I-Exempt	EPY	878.4800 – Speculum, ENT

FF633K FF634K	Curette	I-Exempt	FZS	878.4800 – Curette
OK352K	Nasal Scissors	I-Exempt	KBD	874.4420 – Scissors, Nasal
OL153K	Elevator	I-Exempt	GEG	878.4800 Elevator, Surg., General & Plastic
OK521K	Rongeur	I-Exempt	HTX	888.4540 – Rongeur

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Lisa M. Millington
Regulatory Associate
Aesculap, Inc.
944 Marcon Blvd.
Allentown, Pennsylvania 18109

Re: K003965
Trade Name: MRI Safe Instruments
Regulatory Class: I
Product Code: GEA, GEN
Dated: December 14, 2000
Received: December 22, 2000

Dear Ms. Millington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003965

Device Name: MRI Safe Instruments

Indication for Use:

The MRI Safe Instruments are intended to be used with 1.5 Tesla equipment in (or lower field strength) magnetic resonance imaging procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003965